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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,480	GARRY ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,15-20,27,28 and 31* is/are pending in the application.

4a) Of the above claim(s) *27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 15-20* is/are rejected.

7)☒ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/05; 6/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group 21, claims 1, 2, 15-20 and 31, SEQ ID NO: 30, is acknowledged. Claims 27 and 28 are withdrawn from consideration, being drawn to non-elected subject matter.

Specification

2. The specification is objected to for the following informalities:

- The first paragraph of the specification on page 1 should be amended to include a reference to PCT/US03/35666.
- The brief description of the drawings/figures should include sequence identifiers (SEQ ID NO) for the sequences in the drawings, specifically, Figures 1, 3 and 5.

Claims Summary and Interpretation

3. The claims are drawn to a pharmaceutical composition comprising one or more isolated peptides selected from the following:

a) a peptide comprising SEQ ID NO: 30;

b) a peptide homologous to SEQ ID NO: 30 from another flavivirus; and,

c) a peptide functionally equivalent to SEQ ID NO: 30 that is identical to SEQ ID NO: 30, except that,

- one or more amino acid residues is substituted with a homologous amino acid, resulting in a functionally silent change, or,
- one or more amino acids is deleted.

The specification discloses that SEQ ID NO: 30 is a 42-mer from Dengue virus E protein (Page 8, Table 4). Given the open claim language, "a peptide comprising", the Dengue virus E protein reasonably reads on the claimed invention.

The specification does not appear to provide a definition of the term "homologous". Pages 11-14 of the specification disclose examples of peptide homologs from various flaviviruses, though none appear to be explicitly identified as homologs of SEQ ID NO: 30. Therefore, the Office considers the peptide homologous to SEQ ID NO: 30 to reasonably read on an envelope protein from another flavivirus, or a peptide having a sequence that has one common amino acid residue (or a conservative substitution) with SEQ ID NO: 30.

Another embodiment of the peptide comprising the amino acid sequence of SEQ ID NO: 30, wherein the N-terminal amino acid residue comprises an N-terminal amino group and the C-terminal amino acid residue comprises a C-terminal carboxy group. Note that the Office considers this embodiment to encompass a peptide sequence that is greater in length than SEQ ID NO: 30, based on the transitional language, "having", which is considered the same as "comprising" (open). Another embodiment of the peptide comprises an acetyl group, hydrophobic group, carbobenzoxyl group, dansyl group, t-butyloxycarbonyl group or macromolecular carrier at the N-terminus. Additionally, the C-terminus is an amido group, a hydrophobic group, t-butyloxycarbonyl group, or macromolecular group.

Other embodiments of the peptide include the sequence of SEQ ID NO: 30 wherein at least one bond linking adjacent amino acid residues is a non-peptide bond; wherein at least one amino acid residue is in the D-isomer configuration; at least one amino acid substitution; functional fragment having at least 3 contiguous amino acids of SEQ ID NO: 30. Specifically,

the non-peptide bond is an imido bond, ester bond, hydrazine bond, semicarbazoide bond or azo bond.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15-20 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

- Claim 1 recites, "a peptide functionally equivalent to SEQ ID NO: 30". The claim does not recite the function of SEQ ID NO: 30, thus the function of the functionally equivalent peptide is unknown and cannot be determined. The metes and bounds of the functionally equivalent peptide are not adequately defined.
- Claim 15 and dependent claims recite, "wherein the selected peptide comprises SEQ ID NO: 30". A peptide that simply *comprises* SEQ ID NO: 30 is not one of the peptides listed as a)-f) in claim 2.
- Claim 31 recites, "wherein the selected peptide consists of SEQ ID NO: 30". A peptide that simply consists of SEQ ID NO: 30 is not one of the peptides listed as a)-f) in claim 2.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are summarized above. The specification does not adequately demonstrate possession of embodiments of peptides having any less than the full-length sequence of SEQ ID NO: 30, either in length or amino acid content.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the claims encompass peptides that are homologous to SEQ ID NO: 30 from another flavivirus. The definition of the term "homologous" does not appear to be provided in the specification, thus, the broadest reasonably interpretation is that homologous peptides having a sequence that has one common amino acid residue (or a conservative substitution) with SEQ ID NO: 30. Similarly, the functionally equivalent peptides of SEQ ID NO: 30 having silent mutations or deletions of one or more amino acids are not adequately described because the function is not defined, nor is there any guidance in the specification regarding the limits of deleting amino acids in the functionally equivalent peptide. With regard to the peptide sequence that has one D-isomer residue, the placement of that residue is not disclosed, nor is there any

function that would indicate where the placement of that residue could take place and not disrupt the function of the peptide, whatever that function is. Further, fragments of peptides having 3 contiguous amino acids of SEQ ID NO: 30 are not adequately described because Applicant has not provided any indication of which 3-mer is adequate to perform the desired function, whatever that function is. The specification does not adequately demonstrate possession of the large genus of peptides encompassed by the claim language.

In order to claim SEQ ID NO: 30 as broadly as possible (homologs, functional equivalents, fragments, single substitutions, deletions, D-isomers, various types of bonds, etc.), Applicant must adequately demonstrate possession of a representative number of species of the large genus claimed. Applicant has disclosed SEQ ID NO: 30, a 42-mer of Dengue virus envelope protein, asserted to be a truncated class II fusion protein (page 2, [0006]). Aside from this one sequence, Applicant has not identified any particular portion of the sequence that must be conserved in the homologs, fragments, functional equivalents, etc. Without this information, one of skill in the art would not know where to begin to make these modifications as claimed. For example, the 3-mer functional fragment does not have a function assigned to it in the claim, nor does the specification appear to provide any examples of 3-mers that are functional fragments. This lack of information regarding the 3-mer functional fragment is evidence of lack of adequate written description. Similarly, the functional equivalent of SEQ ID NO: 30 does not have an assigned function, nor does the specification appear to define any other peptides that are functionally equivalent to SEQ ID NO: 30 that have a nearly identical sequence with a few amino acid residues homologously substituted (silent change), or one amino acid deletion all the way to nearly complete deletion of SEQ ID NO: 30. Accordingly, in the absence of sufficient

recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 15, 16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava *et al.* (US Patent 6,117,640, "Srivastava", issued September 12, 2000). The claims

are summarized above. Srivastava discloses a 271-mer sequence comprising Applicant's amino acid sequence, MAILGDTAWDFGSLGGVFTSIGKALHQVFGAIYGAAFSGVSW, SEQ ID NO: 30. The sequence is embedded in Srivastava's SEQ ID NO: 2 as amino acids 124-165. Srivastava's sequence is expected to have an N-terminal amino group and a C-terminal carboxy group, since amino acid sequences naturally have an N-terminal amino group and a C-terminal carboxy group unless intentionally modified. Srivastava's sequence anticipates the claimed invention.

Conclusion

7. Claim 31 is objected to for being dependent on a rejected claim, but would be allowable if rewritten in independent form.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 9-25-2007
Primary Examiner, TC1600